IN THE CIRCUIT COURT OF PRINCE GEORGE'S COUNTY, MARYLAND

MARY ANN CORETTE
5501 Chamberlain Avenue
Chevy Chase, Maryland 20815

and

JOHN CORETTE
5501 Chamberlain Avenue
Chevy Chase, Maryland 20815

Plaintiffs,

v.

DEPUY ORTHOPAEDICS, INC.
700 Orthopaedic Drive
Warsaw, Indiana 46581

Serve: CT Corporation System
150 West Market Street
Suite 800
Indianapolis, IN 46204

and

JOHNSON & JOHNSON SERVICES, INC.
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

and

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

and

DEPUY INTERNATIONAL, LIMITED
St. Anthonys Road
Beeston, Leeds LS11 8 DT
England

and

Case No.:

CAL14-19666

Date Served: 8/5/14
Company Served: Chesapeake Surgical LLC
Certified CT (Personal) Reg. Mail FEDEX NP
Date Rec'd by Law Dept: 8/14/14
Entered into TeamConnect: Yes No
Matter ID #:

DEPUY PRODUCTS, INC.
700 Orthopaedic Drive
Warsaw, Indiana 46581

Serve: CT Corporation System
150 West Market Street
Suite 800
Indianapolis, IN 46204

and

CHESAPEAKE SURGICAL, LTD.
14235 Park Center Drive
Laurel, Maryland 20707

Serve: David W. Donahower
6851 Oak Hall Lane
Suite 204
Columbia, MD 21045

Defendants.

COMPLAINT

COME NOW, Plaintiffs, MARY ANN CORETTE and JOHN CORETTE, by and through their undersigned attorneys and for their Complaint against Defendants, DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON (collectively, "DEPUY"), and CHESAPEAKE SURGICAL, LTD ("CHESAPEAKE"), allege as follows:

INTRODUCTION, PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit over defective hip replacement components implanted in Plaintiff MARY ANN CORETTE which were designed, manufactured, and marketed by DEPUY and marketed, promoted, distributed, and sold by CHESAPEAKE.

2. The particular components at issue in this case were marketed by Defendants as the "DePuy Pinnacle" hip system (hereafter "Pinnacle," "Pinnacle System," or "Pinnacle Device").

3. At all times relevant to this Complaint, MARY ANN CORETTE and JOHN CORETTE ("Plaintiffs"), were and are citizens of the State of Maryland and reside in Chevy Chase, Montgomery County, Maryland.

4. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is, and was at all times relevant herein, doing business in and/or having directed its activities at Prince George's County, Maryland.

5. At all relevant times to this Complaint, DEPUY ORTHOPAEDICS, INC. designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff MARY ANN CORETTE.

6. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY ORTHOPAEDICS, INC. Defendant JOHNSON & JOHNSON SERVICES, INC. is and was at all times relevant herein, doing business in and/or having directed its activities at Prince George's County, Maryland.

7. At all relevant times to this Complaint, Defendant JOHNSON & JOHNSON SERVICES, INC., as the parent company of DEPUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff MARY ANN CORETTE.

8. Defendant JOHNSON & JOHNSON is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY ORTHOPAEDICS, INC. Defendant JOHNSON & JOHNSON is and was at all times relevant herein doing business in and/or having directed its activities at Prince George's County, Maryland.

9. At all relevant times to this Complaint, Defendant JOHNSON & JOHNSON, as the parent company of DEPUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff MARY ANN CORETTE.

10. Defendant DEPUY INTERNATIONAL LIMITED is, and at all times relevant to this Complaint was, a foreign corporation, and a citizen of the United Kingdom with its principal place of business located at St. Anthony's Road, Leeds, LSll 8DT, England. Defendant DEPUY INTERNATIONAL LIMITED is and was at all times relevant herein doing business in and/or having directed its activities at Prince George's County, Maryland.

11. At all relevant times to this Complaint, DEPUY INTERNATIONAL LIMITED designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff MARY ANN CORETTE.

12. Defendant DEPUY INTERNATIONAL LIMITED is a subsidiary of JOHNSON & JOHNSON MEDICAL LIMITED, which is in turn a subsidiary of JOHNSON & JOHNSON.

13. Defendant DEPUY PRODUCTS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581.

14. Defendant CHESAPEAKE is, and at all times relevant to this Complaint was, a Maryland corporation with its principal place of business at 14235 Park Center Drive, Laurel, Maryland 20707. Defendant CHESAPEAKE is, and was at all times relevant herein, doing business in and/or having directed its activities at Prince George's County, Maryland.

15. At all relevant times to this Complaint, CHESAPEAKE promoted, marketed, distributed, and sold the metal-on-metal Pinnacle Device to customers throughout the Washington, D.C. metropolitan area, including Prince George's County, Maryland.

16. Upon information and belief, CHESAPEAKE's relationship with DEPUY is defined in a confidential distributorship agreement.

17. Upon information and belief, at all times relevant to this Complaint, CHESAPEAKE received commissions and intended to financially profit from promoting, marketing, selling, supplying, and distributing DEPUY's products within Prince George's County, Maryland.

18. Upon information and belief, CHESAPEAKE did in fact receive payment from DEPUY in relation to the sale of the hip replacement components sold to and implanted in Plaintiff MARY ANN CORETTE.

19. Within the state of Maryland, CHESAPEAKE is in the chain of distribution for DEPUY products. As such, CHESAPEAKE is a proper defendant in product liability claims involving products they promote, market, sell, supply, or distribute.[1]

20. Jurisdiction is proper in Maryland State Courts because Plaintiffs and all Defendants lack complete diversity.

[1] *See Kelley v. R.G. Industries, Inc.*, 304 Md. 124, 157-58 (Md. 1985)(In a strict liability cause of action, "liability may be imposed against a manufacturer or anyone else in the marketing chain, including the retailer.").

21. Venue is proper in Prince George's County in that at present, and at all times relevant to this Complaint, Defendants do business in Prince George's County.

TOTAL HIP ARTHROPLASTY

22. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons including degenerative bone disease and avascular necrosis.

23. THA involves invasive and traumatic surgery in which a surgeon saws and removes a considerable portion of bone, including the ball, from the top of the femur. In place of the removed bone, the surgeon places a metal shaft, called a "stem," down into what remains of the femoral bone. The portion of the stem which is housed inside the femur may be affixed to the bone via use of bone cement or by a porous coating on the synthetic surface of the stem into which the natural bone will grow. The top of the synthetic metal stem, referred to as the "neck," is not housed inside the femur and remains completely exposed inside the body. A component called a "taper," which can be described as similar to a metal sleeve, fits on top of, and around, the exposed neck of the stem. A synthetic ball, whether made of metal, plastic, or ceramic, is then attached on top of, and around, the taper.

24. The surgeon also replaces the anatomical hip socket, the acetabulum, with an artificial "cup" against which the new, synthetic ball articulates. This cup is sometimes referred to as an "acetabular cup." To implant an acetabular cup, the surgeon removes bone from the natural acetabulum in an effort to create a new hip socket large enough to house the synthetic cup. The surgeon then places the synthetic cup into the newly formed hip socket. The cup affixes to the

bone either through the use of screws, bone cement, a porous metal coating on the back of the synthetic cup into which the natural bone will grow, or by a combination of the three.

25. A successful THA results in a hip prosthesis that should last 30+ years in a patient.

26. If a hip prosthesis fails in a patient, the patient's surgeon may recommend a "revision" THA procedure in order to replace the failed hip components.

27. A revision THA is extremely traumatic to a patient, multitudes more so than a primary THA. The surgery is typically much longer, with greater blood loss, greater surgeon difficulty, and a greater mortality rate. The rehabilitation period for a revision THA can be much longer.

28. In most revision THA procedures, the synthetic components that must be replaced are either the acetabular cup or the femoral ball or both.

29. Further, depending on the mode of failure for a hip prosthesis, the patient's natural anatomy may be so damaged that subsequent revision hip implants will be more likely to fail prematurely.

HIP IMPLANT DESIGN

30. Modern techniques for performing THA and for designing and manufacturing hip replacement components are based on a design introduced by Sir John Charnley in 1962. The design he created and used to perform THA consisted of three components: a one-piece stainless-steel femoral stem and head, an acetabular cup made of Ultra High Molecular Weight Polyethylene (a very hard type of plastic), and acrylic bone cement.

31. Long-term studies of patients undergoing a Charnley THA in the 1960s and early 1970s show excellent results. These studies found that between 85% and 96% of patients still had

a well-functioning Charnley hip 25 years after implant. Another study found that even after 35 years, 78% of patients still did not need to have their original Charnley hip replaced.

32. The Charnley hip was not without its weaknesses. The one piece design of the femoral stem and head did not allow surgeons to adjust the implant for any leg-length discrepancies due to surgery. Also, the design of the acetabular cup required the surgeon to apply bone cement to the back of the cup in order to affix it to the natural hip socket. These design elements contributed to a difficult and inflexible surgical procedure for surgeons. Further, the polyethylene plastic used for the cup could wear off as the stainless steel ball articulated inside and against it. As these plastic particles wore off, they damaged local tissue and bone in the patient and could serve to loosen the acetabular cup from the acetabular bone. However, these shortcomings did not occur often, as evidenced by the design's long term survivorship statistics.

33. Over time, varying designs and various compounds of plastic, ceramic, and metal have been implemented for the stem, femoral head, and the acetabular cup in an effort to improve upon the Charnley design.

34. Briefly, in the 1960s, the orthopedic device industry experimented with various metal-on-metal (hereafter "MoM") designs for hip implants. This design calls for a metal femoral head to articulate directly against the metal interior of an acetabular cup. The perceived benefit of this design was that metal was stronger than plastic and would hopefully last longer and wear less. Further, the strength of the metal would allow for designs that increased range of motion. However, by the mid-1970s, MoM hip implants were completely abandoned in favor of utilizing polyethylene components.

35. Factors that led to the complete abandonment of the MoM designs for hip implants related to:

a. High rates of early revision;
b. The early success of the Charnley prosthesis;
c. Frictional torque between the components;
d. Concerns over the unknown carcinogenic and toxic effects of metal wear;
e. Concerns over metal sensitivity in patients;
f. High rates of infection; and
g. Increased bone strain and fatigue fractures of the bones surrounding the implant.

36. Due to the limited use and subsequent complete abandonment of MoM technology by the mid-1970s, there had been almost no medical or scientific advancement in decades relating to understanding the *actual*, *clinical* risks associated with using MoM technology for hip implants.

37. Despite the MoM hiccup in the evolution of THA surgery, various other improvements have been made to the Charnley design in recent decades.

38. Most modern acetabular cups now implement some form of porous coating on the backside where the cup affixes to the hip socket. This allows for bone to naturally grow into the pores so that the surgeon does not need to use screws or bone cement to seat the cup in the bone.

39. Typically, modern acetabular cups are "modular." This means the cups have multiple components. The components of a modular acetabular cup include the cup, which is implanted into the hip socket, and a "liner" which is placed on the inside of the cup and forms the surface against which the femoral ball articulates.

40. Another improvement was the use of Highly Cross-Linked Ultra High Molecular Weight (HXUHMW) Polyethylene instead of Charnley's original Ultra High Molecular Weight (UHMW) Polyethylene. This improved polyethylene is stronger, harder, and reduces the amount of plastic wear produced during articulation of components.

41. HXUHMW Polyethylene Hip Implants were introduced years prior to DePuy's MoM implant.

42. Modern THA implants typically have a separate femoral stem and femoral head, instead of Charnley's original one-piece design. These two pieces attach at the top of the stem, or "neck." The stem is nearly always made of metal (the particular metal alloy varies depending on manufacturer).

43. The femoral head can be made of HXUHMW Polyethylene or various forms of metal or ceramic.

44. These modern designs have resulted in highly successful implants intended to last and capable of lasting 30+ years in a patient.

THE FDA'S 510(k) CLEARANCE PROCESS

45. In 2000, the U.S. Food and Drug Administration (hereafter "FDA") cleared the DePuy Pinnacle System for sale through its 510(k) clearance process.

46. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug, and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

47. No clinical testing is required under this process.

48. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

49. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

50. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

51. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

52. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

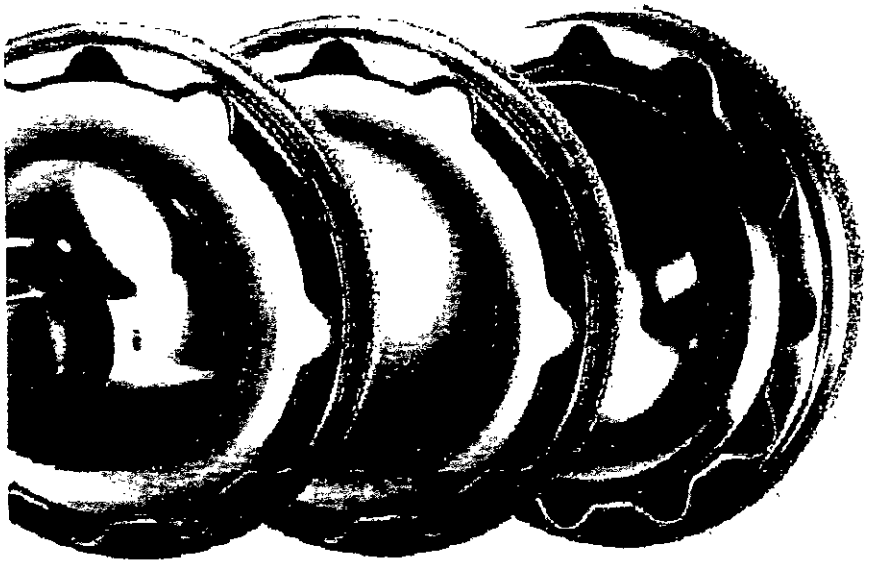
DEPUY PINNACLE HIP SYSTEM

53. DEPUY designs and manufactures various medical devices and implants.

54. In or about 2001, DEPUY began manufacturing the Pinnacle System, and shortly thereafter began promoting, marketing, distributing, selling, and servicing the Pinnacle System.

55. The DePuy Pinnacle System utilizes four main components: a modular metal acetabular cup made of a titanium metal; a liner, made of plastic, ceramic, or cobalt-chromium metal, placed inside of the acetabular cup; a metal femoral head, made of cobalt-chromium; and a metal femoral stem, inserted into the patient's femur. The back of the DePuy Pinnacle acetabular

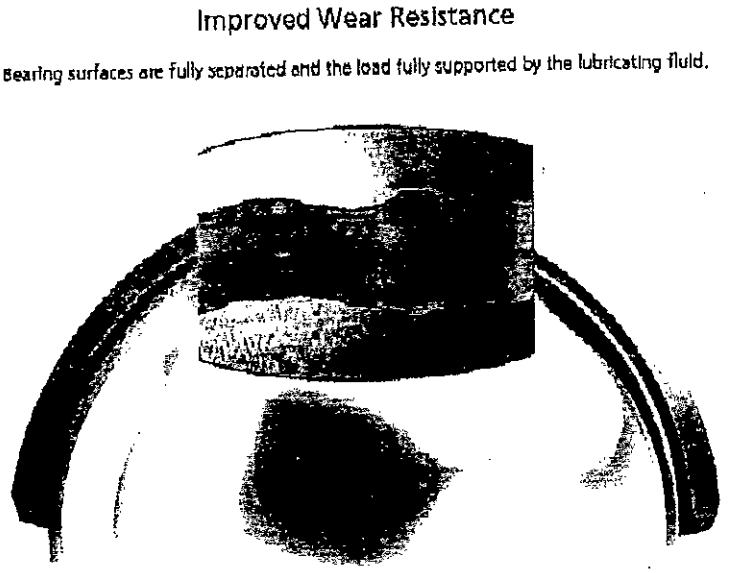
cup utilizes a porous coating intended to promote bone ingrowth and fixation. The femoral ball of the Pinnacle System articulates within the liner, inserted into the acetabular cup. One such liner is made of cobalt chrome, and is known as the "Ultamet" liner. A picture of the Pinnacle System is found below, with the Ultamet liner shown on the far right:



56. In addition to other means, Defendants used brochures and other printed literature to promote the Pinnacle System.

57. Defendants' advertising materials described the Pinnacle as superior to other devices because it featured "TruGlide technology," meant to allow the body to create a thin film of lubrication between surfaces, which "enhances performance with smooth, natural motion and less friction."

58. "Fluid film lubrication" was explained to surgeons as synovial fluid which would operate as a lubricant between the articulating components, preventing them from making any contact with each other. The following is a visualization provided in Defendants' marketing:



59. Defendants also claimed that the Pinnacle hip replacement components would allow "fluid film lubrication, enhanced stability and low wear while preserving acetabular bone."

60. Defendants disseminated literature to the orthopedic community stating that the Pinnacle components were "uniquely designed to meet the demands of active patients like you – and help reduce pain," and that the Pinnacle "recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

61. Defendants' marketing of the Pinnacle System suggested the Pinnacle System was so effective that Pinnacle recipients could partake in challenging and vigorous athletic activities. A few photographs used in the marketing are included below:

a. A man running on the beach, carrying a large surfboard.

b. A man taking an aggressive golf swing.

c. A woman exercising on an elliptical machine.

d. A man hiking on rough, uneven terrain while carrying a large backpack.

62. DEPUY utilized distributors and sales representatives, including CHESAPEAKE, who were responsible for educating Plaintiff MARY ANN CORETTE's orthopedic surgeon regarding the claimed advantages of the products used, answering any questions her orthopedic surgeon asked regarding the products, assisting Plaintiff MARY ANN CORETTE's orthopedic surgeon at surgery regarding the products, and selling the products to Plaintiff MARY ANN CORETTE through her orthopedic surgeon agent.

63. CHESAPEAKE trained and educated their sales staff regarding the DePuy Pinnacle System, including orthopedic and surgical training, product design rationale, surgical technique tips, training in the use of implanting tools, training in selecting the hip replacement components to mate with the Pinnacle System, and training on how to sell to orthopedic surgeons, including training on the advantage of the Pinnacle System over its competitors.

64. Prior to Plaintiff MARY ANN CORETTE's THA surgery, sales representatives of CHESAPEAKE provided information to her orthopedic surgeon, including but not limited to, the advantages of the Pinnacle System compared to its competitors, information regarding the design rationale for the Pinnacle System, surgical techniques on how to implant the Pinnacle System, and demonstrations on how to implant the Pinnacle System and the components that could best be mated with the Pinnacle System, including providing a variety of scenarios involving the various instrumentation used in implanting the Pinnacle System.

65. These sales representative agents were responsible for answering any questions or concerns Plaintiff MARY ANN CORETTE's orthopedic surgeon had regarding the Pinnacle System.

66. The sales representative agents' communications to the orthopedic community, including Plaintiff MARY ANN CORETTE's surgeon, were not limited to information provided on the Pinnacle Device packaging or labeling.

67. The above communications and information were provided to Plaintiff MARY ANN CORETTE's orthopedic surgeon with the intended purpose of convincing and inducing Plaintiff MARY ANN CORETTE's orthopedic surgeon to use the Pinnacle System instead of one of the competing hip replacements.

68. At all times relevant to this Complaint, Plaintiff MARY ANN CORETTE's orthopedic surgeon, nurses and hospital staff relied on information and assistance from CHESAPEAKE and their sales representative agents.

69. In preparation for Plaintiff MARY ANN CORETTE's implant surgery, Plaintiff MARY ANN CORETTE's orthopedic surgeon (or someone at the surgeon's direction) contacted Defendants to notify Defendants of the need for the Pinnacle System components.

70. Defendants, through CHESAPEAKE, selected and provided the specific components to be used during the surgery and delivered them to the operating room where Plaintiff MARY ANN CORETTE's implant surgery took place.

PROBLEMS WITH THE DEPUY PINNACLE HIP SYSTEM

71. Defendants did not clinically test the Pinnacle System for safety prior to its release.

72. Despite Defendants' claims of the advantages of the Pinnacle System, the product is and always was deeply flawed and defective.

73. The testing done on the product prior to launch was woefully inadequate and not representative of real-world, clinical situations.

74. Defendants marketed the Pinnacle Device as safe merely based on a lack of conclusive clinical connection to cancer and other hazards, as opposed to an affirmative clinical determination of safety.

75. Indeed, Defendants knew that there was no *clinical* evidence to support the contention that the device was safe or effective.

76. Upon information and belief, prior to Plaintiff MARY ANN CORETTE's implant and revision surgeries, Defendants were aware of defects and unreasonably high rates of problems with the Pinnacle System, including, but not limited to, high levels of metal wear causing local and or systemic damage in patients' bodies, metallosis, tissue death, bone erosion, the development of pseudotumors, elevated cobalt and chromium levels, component loosening, component locking, dislocation, and particulate debris resulting in severe inflammation, severe pain, tissue and bone loss, and other related diseases.

77. Despite its marketing, the Pinnacle System did not facilitate fluid film lubrication between the articulating components. As such, with the use of the Ultamet liner, the metal components articulated directly against each other during clinical use and resulted in excessive rates of metal wear.

78. Defendants marketed the Pinnacle System despite not knowing the safety implications of metal wear released from the device.

79. Prior to marketing and selling the Pinnacle System, Defendants knew or should have known that the Pinnacle System was not a clinically safe prosthesis.

80. Despite knowing, or being in a position where they should have known of the unreasonable risks associate with the Pinnacle System, Defendants began to market and sell the Pinnacle System in or around 2001.

81. Since its inception, the Pinnacle System experienced an unreasonably high rate of failure worldwide.

82. During the marketing and sale of the Pinnacle System, Defendants knew or should have known that the system was not a clinically safe prosthesis.

83. No official government registry exists in the United States to which surgeons report orthopedic implant failures or revisions.

84. Accordingly, Defendants are typically the only entities to whom surgeons, including Plaintiff MARY ANN CORETTE's surgeon, report failures or revisions of the products at issue in this Complaint.

85. A number of governmental regulatory agencies have recognized the problems caused by metal-on-metal implants such as the Pinnacle System. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom investigated Defendants' metal-on-metal total hip replacement systems after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

86. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance, and treatment of all patients who had received these and similar metal-on-metal implants.

87. Despite the public knowledge to the contrary, Defendants continued to misrepresent the Pinnacle Device as a high-quality, safe, and effective hip replacement product

in their marketing and promotional materials. This was despite the fact that Defendants knew for years that the Pinnacle Device posed an unreasonable danger to patients.

88. Despite knowledge of its unreasonable risks, Defendants continued to sell the Pinnacle System to doctors who implanted them in countless numbers of patients. An unreasonably high percentage of those patients are forced to endure serious injury from the device. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

89. By August 31, 2013, sales of the Pinnacle Device had plummeted due to the medical community's fear of using a product associated with such unreasonable danger. Citing these decreased sales, rather than the known risk of danger, Defendants finally stopped selling the Pinnacle Device on that date.

90. The Pinnacle System was more dangerous than an ordinary consumer would reasonably expect, and the risks associated with it were more dangerous than the risks associated with other hip replacement devices that were available to treat Plaintiff MARY ANN CORETTE's condition.

PLAINTIFF MARY ANN CORETTE'S IMPLANT AND NEED FOR REVISION

91. Plaintiff MARY ANN CORETTE experienced a history of pain and disease in her left hip that caused her to be treated by Charles A. Engh, M.D. ("Dr. Engh").

92. Dr. Engh determined Plaintiff MARY ANN CORETTE needed a THA of her left hip.

93. On February 26, 2003, Dr. Engh performed a THA on Plaintiff MARY ANN CORETTE's left hip at Inova Mount Vernon Hospital in Alexandria, Virginia.

94. During this THA, Dr. Engh implanted Plaintiff MARY ANN CORETTE with a number of DePuy Pinnacle components, including:

a. Acetabular Cup: DePuy Pinnacle acetabular cup, 54mm.
b. Acetabular Liner: Ultamet Liner, 36mm.
c. Femoral Head: DePuy Unipolar femoral head, 36mm.

95. After being implanted with the Pinnacle System, Plaintiff MARY ANN CORETTE sought follow-up treatment with William G. Hamilton, M.D. ("Dr. Hamilton").

96. Dr. Hamilton discovered that Plaintiff MARY ANN CORETTE had elevated metal ion levels and subsequently recommended revision surgery.

97. Plaintiff MARY ANN CORETTE underwent revision surgery on February 13, 2014 to replace her femoral ball and acetabular liner under the care of Dr. Hamilton at Inova Mount Vernon Hospital. In this surgery, Dr. Hamilton discovered the effects of metal debris. In the operative report, Dr. Hamilton stated that, "there was mild to moderate amount of necrotic tissue within the capsule."

98. Dr. Hamilton's preoperative and postoperative diagnoses were, "Left total hip metal-on-metal reaction."

99. Following the February 13, 2014 revision of her femoral ball and acetabular liner, Plaintiff MARY ANN CORETTE suffered two dislocations. The first dislocation required a closed reduction on April 3, 2014, performed by Robert Buber, M.D. at Suburban Hospital in Bethesda, Maryland.

100. Plaintiff MARY ANN CORETTE's second dislocation necessitated the revision of her acetabular cup on April 29, 2014, performed by Dr. Hamilton at Inova Mount Vernon Hospital.

101. Plaintiff MARY ANN CORETTE is now in the slow process of recovering from this traumatic revision.

PLAINTIFF MARY ANN CORETTE'S INJURIES

102. Upon information and belief, the aforementioned defects with the DePuy Pinnacle System caused Plaintiff MARY ANN CORETTE's DePuy Pinnacle System to fail prematurely, causing elevated metal ion levels.

103. Plaintiff MARY ANN CORETTE suffered injuries as a result of the negligent design, manufacture, marketing and distribution of the DePuy Pinnacle System and component parts.

104. As a direct and proximate result of the failed DePuy Pinnacle System, Plaintiff MARY ANN CORETTE was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

105. As a direct and proximate result of the failed DePuy Pinnacle System, Plaintiff MARY ANN CORETTE was required to have a revision surgery, suffered additional scar tissue, suffered dislocations necessitating further revision, and now has a left hip implant with decreased longevity.

106. Plaintiff MARY ANN CORETTE suffered personal injuries, including experiencing great pain and suffering, as a result of the defective DePuy Pinnacle System. Plaintiff MARY ANN CORETTE continues to experience pain and suffering and will experience additional pain and suffering in the future.

107. As a direct and proximate result of the failed DePuy Pinnacle System, Plaintiff MARY ANN CORETTE experienced emotional trauma and distress, and is likely to experience emotional trauma and distress in the future.

COUNT ONE – STRICT LIABILITY: DESIGN DEFECT (ALL DEFENDANTS)

108. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

109. Defendants designed (DEPUY only), manufactured (DEPUY only), marketed, advertised, and sold the defective product at issue in addition to providing training materials to sales agents and surgeons on properly selecting and implanting the defective product.

110. The product was unreasonably dangerous as designed, marketed, advertised and sold.

111. The product was unreasonably dangerous based on the training given to sales agents and surgeons regarding the product.

112. There was no substantial change in the condition of the products from the time they left Defendants' possession to the time they were sold to and implanted in Plaintiff MARY ANN CORETTE.

113. The product was unreasonably dangerous when sold to and implanted in Plaintiff MARY ANN CORETTE.

114. The unreasonable danger posed to Plaintiff MARY ANN CORETTE by Defendants' product directly and proximately caused Plaintiff MARY ANN CORETTE's injuries, as described in paragraphs 102-107, above.

COUNT TWO – STRICT LIABILITY: MANUFACTURING DEFECT (ALL DEFENDANTS)

115. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

116. Defendants designed (DEPUY only), manufactured (DEPUY only), marketed, advertised, and sold the defective product at issue in addition to providing training materials to sales agents and surgeons on properly selecting and implanting the defective product.

117. The product was unreasonably dangerous as manufactured, marketed, advertised and sold because it was not made in accordance with Defendants' specifications or performance standards.

118. The product was unreasonably dangerous based on the training given to sales agents and surgeons regarding the product.

119. There was no substantial change in the condition of the product from the time it left Defendants' possession to the time it was sold to and implanted in Plaintiff MARY ANN CORETTE.

120. The product was unreasonably dangerous when sold to and implanted in Plaintiff MARY ANN CORETTE.

121. The unreasonable danger posed to Plaintiff MARY ANN CORETTE by Defendants' product directly and proximately caused Plaintiff MARY ANN CORETTE's injuries, as explained in paragraphs 102-107, above.

COUNT THREE – STRICT LIABILITY: FAILURE TO WARN (ALL DEFENDANTS)

122. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

123. Defendants designed (DEPUY only), manufactured (DEPUY only), marketed, advertised, and sold the defective product at issue in addition to providing training materials to sales agents and surgeons on properly selecting and implanting the defective product.

124. Defendants had a duty to adequately warn Plaintiff MARY ANN CORETTE of particular known or knowable risks in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

125. Defendants failed to adequately warn Plaintiff MARY ANN CORETTE of particular known or knowable risks in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

126. The product was unreasonably dangerous as designed, marketed, advertised and sold.

127. The product was unreasonably dangerous based on the training given to sales agents and surgeons regarding the product.

128. There was no substantial change in the condition of the product from the time it left Defendants' possession to the time it was sold to and implanted in Plaintiff MARY ANN CORETTE.

129. The product was unreasonably dangerous when sold to and implanted in Plaintiff MARY ANN CORETTE.

130. Defendants had a continuing duty to adequately warn Plaintiff MARY ANN CORETTE of particular known or knowable risks in light of the generally recognized and prevailing best scientific and medical knowledge that became available during Plaintiff MARY ANN CORETTE's exposure to Defendants' product.

131. Defendants failed to adequately warn Plaintiff MARY ANN CORETTE of particular known or knowable risks in light of the generally recognized and prevailing best scientific and medical knowledge that became available during Plaintiff MARY ANN CORETTE's exposure to Defendants' product.

132. As a result of Defendants' continuing failure to adequately warn Plaintiff MARY ANN CORETTE of known or knowable risks in light of the generally recognized and prevailing best scientific and medical knowledge, Defendants' product became or continued to be unreasonably dangerous to Plaintiff MARY ANN CORETTE.

133. Defendants had a duty to adequately warn Plaintiff MARY ANN CORETTE or her surgeon if any of Plaintiff MARY ANN CORETTE's medical conditions or medical history presented a contraindication for the implanting of Defendants' product.

134. Defendants failed to adequately warn Plaintiff MARY ANN CORETTE or her surgeon if any of Plaintiff MARY ANN CORETTE's medical conditions or medical history presented a contraindication for the implanting of Defendants' product.

135. The unreasonable danger posed to Plaintiff MARY ANN CORETTE by Defendants' product due to Defendants' failure to adequately warn Plaintiff MARY ANN CORETTE directly and proximately caused Plaintiff MARY ANN CORETTE's injuries, as explained in paragraphs 102-107, above.

COUNT FOUR – NEGLIGENCE (ALL DEFENDANTS)

136. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

137. Defendants had a duty of reasonable care in designing (DEPUY only), testing (DEPUY only), manufacturing (DEPUY only), marketing, advertising, and selling the product.

138. Defendants had a duty of reasonable care in training sales agents and surgeons regarding the product.

139. Defendants had a duty of reasonable care in warning Plaintiff MARY ANN CORETTE of defects and known or knowable particular risks of the product not outwardly apparent to Plaintiff MARY ANN CORETTE.

140. Defendants breached each of these duties.

141. As a direct and proximate result of Defendants' breach of their duty of reasonable care, Plaintiff MARY ANN CORETTE was injured as explained in paragraphs 102-107, above.

COUNT FIVE – NEGLIGENT MISREPRESENTATION (ALL DEFENDANTS)

142. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

143. Defendants, in the course of their business, profession or employment, or in any other transaction in which Defendants had a pecuniary interest, had a duty to exercise reasonable care or competence in obtaining or communicating information pertaining to the safety, clinical history, wear rates, and effectiveness of their product.

144. Defendants, in the course of their business, profession, or employment, or in any other transaction in which Defendants had a pecuniary interest, failed to exercise reasonable care or competence in obtaining or communicating information pertaining to the safety, clinical history, wear rates, and effectiveness of the product.

145. Defendants, in the course of their business, profession, or employment or in any other transaction in which Defendants had pecuniary interest, supplied false information to Plaintiff MARY ANN CORETTE and her surgeon relating to the product's safety, clinical history, wear rates, and effectiveness.

146. Defendants intended that Plaintiff MARY ANN CORETTE and her surgeon rely on Defendants' false information.

147. Plaintiff MARY ANN CORETTE and her surgeon justifiably relied on Defendants' false information.

148. As a result of this justifiable reliance on Defendants' false information, Plaintiff MARY ANN CORETTE was injured as explained in paragraphs 102-107, above.

COUNT SIX – BREACH OF EXPRESS WARRANTY (DEPUY DEFENDANTS)

149. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

150. DEPUY designed, manufactured, marketed, advertised, and distributed into the stream of commerce the product at issue in this case.

151. Further, DEPUY managed a sales training regime to train sales agents and implanting surgeons on advantages of the product and proper patient selection and implanting techniques.

152. DEPUY expressly warranted to Plaintiff MARY ANN CORETTE and her surgeon that the product at issue was a safe and effective hip replacement system.

153. These warranties became part of the basis of the bargain between DEPUY and Plaintiff MARY ANN CORETTE.

154. The product at issue in this case did not conform to DEPUY's express representations because the amount of metal wear the product releases into the human body is unreasonably toxic, unsafe, and causes the product to fail at an unacceptable rate.

155. As a direct and proximate result of DEPUY's breach of express warranties regarding the safety and effectiveness of the product, Plaintiff MARY ANN CORETTE was injured as explained in paragraphs 102-107, above.

COUNT SEVEN – BREACH OF IMPLIED WARRANTY (DEPUY DEFENDANTS)

156. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

157. DEPUY is in the business of designing, manufacturing, supplying, and placing into the stream of commerce the product at issue in this case.

158. By placing the product into the stream of commerce, DEPUY impliedly warranted that the product was merchantable and fit and safe for its intended use.

159. The product placed into the stream of commerce by DEPUY and implanted in Plaintiff MARY ANN CORETTE, was defective and accordingly was not fit, safe, or merchantable for its intended use.

160. The defects in the product were present at the time the product left DEPUY's control.

161. DEPUY breached the implied warranty for the product because it was defective and not fit, safe, or merchantable for its intended use.

162. Plaintiff MARY ANN CORETTE was a foreseeable user of the product at issue in this case.

163. Plaintiff MARY ANN CORETTE purchased the product in the stream of commerce.

164. Plaintiff MARY ANN CORETTE is in privity with DEPUY.

165. As a direct and proximate result of DEPUY's breach of implied warranties, Plaintiff MARY ANN CORETTE was injured as explained in paragraphs 102-107, above.

COUNT EIGHT – LOSS OF CONSORTIUM (ALL DEFENDANTS)

166. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

167. Plaintiff JOHN CORETTE was, at all times relevant to this Complaint, and is currently the lawful husband of Plaintiff MARY ANN CORETTE.

168. As a direct and proximate result of the conduct of Defendants as set forth above, and of the injuries and damages suffered by Plaintiff MARY ANN CORETTE, Plaintiff JOHN CORETTE suffered and will continue to suffer the loss of care, services, companionship, counsel, advice, assistance, comfort, and consortium of his wife, Plaintiff MARY ANN CORETTE, and has incurred, and will continue to incur in the future, expenses for the care and treatment of his wife, Plaintiff MARY ANN CORETTE, and has provided and will continue to provide extraordinary services in order to care for his wife, all to his loss and damage.

COUNT EIGHT – VIOLATION OF MARYLAND CONSUMER PROTECTION ACT (ALL DEFENDANTS)

169. Plaintiffs re-allege and incorporate by reference paragraphs 1-107 above as if fully stated herein.

170. Defendants used deception, misrepresentation, and omission to convince Plaintiff MARY ANNE CORETTE's orthopedic surgeon, acting as her agent, that the components at issue were safe, effective, and superior other products readily available for use.

171. Defendants used deception, misrepresentation, and omission to convince Plaintiff MARY ANNE CORETTE's orthopedic surgeon, acting as her agent, to purchase the components at issue on behalf of Plaintiff MARY ANNE CORETTE and implant them in her.

172. As a result, Plaintiff MARY ANNE CORETTE purchased the product for personal use.

173. As a direct and proximate result of Defendants deceptive acts and omissions, Plaintiff MARY ANNE CORETTE suffered injuries as described specifically in paragraphs 104-109.

WHEREFORE, Plaintiff MARY ANNE CORETTE respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

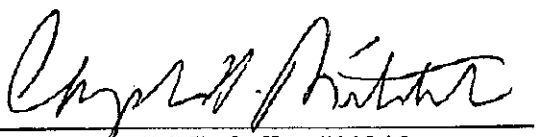
DEMAND FOR JURY TRIAL

Plaintiffs respectfully request that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants for compensatory damages and any other relief the Court deems just and proper.

Dated this 22nd day of July, 2014.



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